

REMARKS/ARGUMENTS

Claims 1-17 are pending in this application. Claims 1-17 are subject to restriction and/or election requirement.

The Examiner has required restriction among the following Groups:

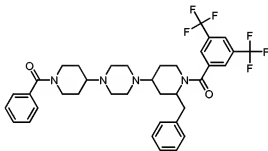
- I. Group I, claim(s) 1-11, are drawn to a pharmaceutical composition comprising a pharmaceutically acceptable carrier and, as active ingredients, an opioid analgesic and a therapeutically effective amount of a compound according to Formula (I).
- II. Group II, claim(s) 12-15, are drawn to the use of a pharmaceutical composition according to any one of claims 1 to 11 for the manufacture of a medicament for the prevention and/or treatment of pain and/or nociception.
- III. Group III, claim(s) 16, are drawn to the use of an NK<sub>1</sub>-receptor antagonist, in particular an NK<sub>1</sub>-receptor antagonist according to Formula (I), the pharmaceutically acceptable acid or base addition salts thereof, the stereochemically isomeric forms thereof, the N-oxide form thereof and prodrugs thereof, for the manufacture of a medicament for the prevention and/or treatment of respiratory depression in opioid-based treatments of pain.
- IV. Group IV, claim(s) 17, are drawn to the use of an NK<sub>1</sub>-receptor antagonist, in particular an NK<sub>1</sub>-receptor antagonist according to Formula (I), the pharmaceutically acceptable acid or base addition salts thereof, the stereochemically isomeric forms thereof, the N-oxide form thereof and prodrugs thereof, for the manufacture of a medicament for reducing and/or overcoming the tolerance observed with opioids in opioid-based treatments of pain.

Applicants elect the subject matter of the Examiner's Group I, i.e. claims 1-11, for further prosecution in this application. This election is made with traverse. Applicants have been requested to elect one specific species from the generic invention. Since all of the claims in

Group I are drawn to a pharmaceutical composition comprising a carrier and an opioid and a compound of Formula (I) as active ingredients, applicants assume that the requested species is a specific species from the generic structure Formula (I) set forth in claim 1.

Applicants elect as the specific species the following compound:

{4-[4-(1-Benzoyl-piperidin-4-yl)-piperazin-1-yl]-2-benzyl-piperidin-1-yl}-(3,5-bis-trifluoromethyl-phenyl)-methanone, which has the following structure:



{4-[4-(1-Benzoyl-piperidin-4-yl)-piperazin-1-yl]-2-benzyl-piperidin-1-yl}-(3,5-bis-trifluoromethyl-phenyl)-methanone .

In addition to the above election, applicants are required to elect a species from the various opioid analgesics. Applicants elect morphine as the specific opioid species. Claims 1-17 read on the elected species.

The above election is made with traverse.

In requiring restriction among Groups I-IV the Examiner has concluded that Groups I-III do not relate to a single inventive concept under PCT Rule 13.2 because they lack the same or corresponding special technical features in that the claims lack an inventive step over U.S. patent 6,197,772B which discloses piperidinyl piperazine derivatives and their use in the treatment of chronic neuropathic pain and emesis induced by opioids such as morphine. The Examiner has concluded further that there is a lack of unity of invention among the various groups.

Applicants' invention relates to pharmaceutical compositions for the treatment of emesis in opioid based treatments of pain and/or nociception comprising an opioid analgesic and certain piperazine derivatives having neurokinin antagonistic activity in a pharmaceutically acceptable carrier. The claimed compositions reduce to a large extent the unwanted side-effects associated with opioid analgesics. Claims 12-17 were amended in the Preliminary Amendment filed on 12/12/05 by converting claims drawn to the use of the pharmaceutical composition to manufacture a medicament for treating pain to claims using the pharmaceutical composition to treat pain. Therefore, Groups II-IV are drawn to methods of using the composition claimed in Group I for the treatment of pain. Since the compounds employed in the compositions of Group I are the same compounds employed in the method of treatment claims of Groups II-IV, it is submitted that the examination of Groups I-IV in the same application would not be unduly burdensome for the Examiner since the search for each of the Groups would be essentially the same. It seems proper, therefore, to examine the compositions and the method of using the compositions in a single application.

As indicated above Group II (claims 12-15), Group III (claim 16) and Group IV (claim 17) are all drawn to a method of using the compositions claimed in claims 1-11. Since all of the claimed uses for the claimed compositions relate to the treatment of pain, applicants submit that Groups II-IV constitute a single group and, therefore, should be prosecuted as a single group instead of three separate groups.

Reconsideration of the Restriction Requirement under 35 U.S.C. 121 and 372 is courteously requested.

The Examiner has indicated that restriction was required between product and process claims. As indicated above claims 1-11 are drawn to pharmaceutical compositions while claims 12-17 are drawn to the use of the claimed compositions in the treatment of pain and/or nociception. There are no process claims *per se* in the application unless the Examiner regards the method of treatment claims to be process claims.

Applicants request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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